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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FENWICK & WEST LLP  
SILICON VALLEY CENTER  
801 CALIFORNIA STREET  
MOUNTAIN VIEW, CA 94041

EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/955,663

Applicant(s)

ROCKE ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                         |                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>20060406</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.                                                                      |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not reiterated below are hereby withdrawn. Applicant's arguments with regard to the equations of ROCKE are persuasive, therefore the rejections under 35 USC 103 are hereby withdrawn.

***Claim Rejections - 35 USC § 101***

The rejection with regard to non-statutory subject matter is hereby withdrawn in view of the amendment to claim 2 of an "inputting" step, argued by applicant in the response filed 2/7/06 to be a physical step. Applicant is reminded, however, that deletion of this step may result in reinstatement of the rejection as the claims still do not recite a concrete, tangible and useful result.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> para.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Steps of inputting a set of gene expression data, of identifying subsets of data, estimating a standard deviation for the entirety of a set of gene expression data, as recited in amended claim 2, are all new matter.

In the response filed 2/7/06, applicant points to page 12 of the specification for support for the “inputting” step. The original claims did not recite any input step. Page 12 does not teach inputting of data of any kind, specifically gene expression data. Page 12 of the originally filed specification teaches obtaining samples and performing hybridization assays, but does not specifically teach obtaining, measuring ,etc. *gene expression data*. Page 12 further teaches statistical analysis, and while the data analyzed is not explicitly identified as that obtained from the hybridization experiments, it is a logical conclusion to draw. It is noted that data need not be input in order to be analyzed if the data from the hybridization experiments are “read” directly by a computer. In fact, it is common in most scientific arts to use computerized or computer-linked instruments to both read and analyze data resulting from assays wherein data does not require physical “input.” Thus, the disclosure of page 12 for running a hybridization assay followed by statistical analysis does not inherently include and “inputting” step and does not provide support for the newly recited step of claim 2.

Applicant points to pages 2 and 6 for support for “identifying a first subset ...” “identifying a second subset...” Nowhere do the original claims or the originally filed specification specifically disclose subsets of gene expression data. Page 2 and original claim 2 both support identifying a set of low level data measurements; wherein page 2 also provides support that these are observed intensity measurements.. Page 6 and

Art Unit: 1631

original claim 2 also provide support for identifying replicated high-level data; wherein page 6 also provides support that these are intensity measurements. However, the specification does not identify either the low or high level data as a subset of a larger set wherein a second subset may also be derived from the same larger dataset, as is now claimed.

Applicant points to pages 2-3 for support for “estimating a standard deviation ...of the set of gene expression data.” Original claim 2 recited only estimation of a standard deviation from a high-level data set and therefore does not provide support for estimating a standard deviation from a low-level set. Page 2 of the originally filed specification first discloses identifying low level intensity measurements then specially states that two parameters are estimated from “this set of data.” The parameters are mean intensity of unexpressed genes and a standard deviation. The specification thus teaches that the standard deviation is calculated for the set of low-level measurements just identified, not for the entirety of a set of gene expression measurements.

As the originally filed disclosure does not provide support for the amendments to claim 2 for the reasons set forth above, the claims are rejected for reciting new matter.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> para.***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claims 2-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a step of identifying a second subset of data in step (d) wherein the second subset of data comprises several specified measurements of the set "or the variance of logarithms of the second subset is approximately constant, " which is nonsensical. The last two lines of step (d) do not appear to have any relationship to the rest of the step and it is unclear what limitation is intended, therefore the phrase renders the claim indefinite.

### ***Conclusion***

Claims 2-12 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1631

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
4/6/08